UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/055,863	01/22/2002	Heidrun Engler	016930-000816US	4929

20350 7590 10/24/2003

TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
WILSON, MICHAEL C	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 10/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/055,863	ENGLER ET AL.	
	Examiner	Art Unit	
	Michael C. Wilson	1632	

-- Th MAILING DATE of this communication appears on the cov r she t with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-81* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-81* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, 26 and 27, drawn to a method of delivering protein using the compound of Formula I, classified in class 424 in various subclasses.

II. Claims 1-9, 11-27, 61-75 and 80, drawn to a method of delivering a gene using the compound of Formula I, classified in class 514, subclass 44, and class 435, subclass 325.

III. Claims 28-58, drawn to a composition comprising Formula I, classified in class 552, subclass 509.

IV. Claims 59-60, drawn to a delivery enhancing composition comprising Formula II, classified in class 552, subclass 509.

V. Claims 76 and 81 drawn to a method of treating bladder cancer using a composition comprising Formula III and a viral vector, classified in class 424, subclass 93.1.

VI. Claim 77, drawn to a method of treating bladder cancer using a composition comprising Formula IV and a viral vector, classified in class 424, subclass 93.1.

VII. Claim 78, drawn to a method of treating bladder cancer using a composition comprising Formula V and a viral vector, classified in class 424, subclass 93.1.

VIII. Claim 79, drawn to a method of treating bladder cancer using a composition comprising Formula II and a viral vector, classified in class 424, subclass 93.1.

The inventions are distinct, each from the other because of the following reasons:

Groups I and II are patentably distinct because the purpose of delivering proteins is to avoid using intracellular machinery to express the protein while the purpose of delivering genes is to use intracellular machinery to express the protein. In addition, nucleic acids sequences such as antisense may be delivered to inhibit protein expression. The protocols and reagents for proteins and genes are materially distinct and separate. The method of delivering proteins does not require delivering genes and the method of delivering genes does not require delivering proteins.

Groups I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process can be practiced with Formula II, III, IV or V or with protein instead of genes. The product of Group III can also be used to deliver proteins.

Groups I and IV are patentably distinct because Group I requires Formula I while Group IV requires Formula II. The composition comprising Formula II can be used to deliver genes instead of proteins as in Group I. The protocols and reagents for proteins

and genes are materially distinct and separate. The method of delivering proteins does not require Formula II and composition in Group IV does not require delivering proteins.

Groups I and V, VI, VII or VIII are patentably distinct because the purpose of Group I is to delivery protein while the purpose of Groups V, VI, VII, or VIII is to deliver genes. The protocols and reagents for proteins and genes are materially distinct and separate. The method of delivering proteins does not require delivering viral vectors and the method of delivering viral vectors does not require delivering proteins. The method of delivering proteins does not require delivering Formulas II, III, IV or V and the method of delivering viral vectors using Formulas II, III, IV or V does not require Formula I.

Groups II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of Group II can also be practiced using Formula II, III, IV or V instead of Formula I. The method of Group II can also be practiced using protein instead of a gene. The product of Group III can be used to deliver proteins instead of genes as in Group II. While claims 36-39 in Group III require using the composition to deliver polynucleotides, such a limitation is an intended use and does not bear patentable weight because it may not occur. The body of claims 36-39 does not require the composition comprise a polynucleotide.

Groups II and IV are patentably distinct because Group II requires Formula I while Group IV requires Formula II. The composition comprising Formula II (Group IV) can be used to deliver proteins instead of genes. The protocols and reagents for proteins and genes are materially distinct and separate. The method of delivering genes does not require Formula II and composition in Group IV does not require delivering genes.

Groups II and V, VI, VII or VIII are patentably distinct because Group II requires Formula I while the Groups V, VI, VII, or VIII require Formula II, III, IV or V. The structure and function of Formulas I-V are materially distinct and separate. The method of Group II does not require Formulas II, III, IV or V and the method of Groups V-VIII does not require Formula I. The burden required to search Formulas I-V together would be undue.

Groups III and IV are patentably distinct because Group III requires Formula I while Group IV requires Formula II. The composition comprising Formula II (Group IV) can be used to deliver proteins instead of genes as in claims 36-39. The protocols and reagents for proteins and genes are materially distinct and separate. The composition of Group III does not require Formula II and composition in Group IV does not require Formula I. The burden required searching Formulas I and II together would be undue. While claims 36-39 in Group III require using the composition to deliver polynucleotides, such a limitation is an intended use and does not bear patentable weight because it may not occur. The body of claims 36-39 does not require the composition comprise a polynucleotide.

Groups III and V, VI, VII or VIII are patentably distinct because Group III requires Formula I while the Groups V, VI, VII, or VIII require Formula II, III, IV or V. The purpose of the composition of Group III may be to deliver proteins while the purpose of Groups V, VI, VII and VIII is to treat bladder cancer. The structure and function of Formulas I-V are materially distinct and separate. The composition of Group III does not require Formulas II, III, IV or V and the method of Groups V-VIII does not require Formula I. The method of Group III does not require treating bladder cancer. The burden required to search Formulas I-V together would be undue.

Groups IV and V, VI or VII are patentably distinct because the composition of Group IV requires Formula II while the method of Groups V, VI and VII requires Formulas III, IV and V. The purpose of the composition of Group IV may be to deliver proteins while the purpose of Groups V, VI and VII is to treat bladder cancer. The structure and function of Formulas II-V are materially distinct and separate. The composition of Group IV does not require Formulas III, IV or V and the method of Groups V-VII does not require Formula II. The method of Group IV does not require treating bladder cancer. The burden required to search Formulas II-V together would be undue.

Inventions IV and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can

be used to deliver proteins. In addition, the process can be used with Formula III, IV or V instead of Formula II.

Groups V and VI are patentably distinct because the method of Group V requires Formula III while the method of Group VI requires Formula IV. Thus, the methods have different modes of operation. The structure and function of Formula III and IV are materially distinct and separate. The method of Group V does not require Formula IV and the method of Group VI does not require Formula III. The burden required to search the method using either Formula III or IV would be undue.

Groups V and VII are patentably distinct because the method of Group V requires Formula III while the method of Group VII requires Formula V. Thus, the methods have different modes of operation. The structure and function of Formula III and V are materially distinct and separate. The method of Group V does not require Formula V and the method of Group VII does not require Formula III. The burden required to search the method using either Formula III or V would be undue.

Groups V and VIII are patentably distinct because the method of Group V requires Formula III while the method of Group VIII requires Formula II. Thus, the methods have different modes of operation. The structure and function of Formula III and II are materially distinct and separate. The method of Group V does not require Formula II and the method of Group VIII does not require Formula III. The burden required to search the method using either Formula III or II would be undue.

Groups VI and VII are patentably distinct because the method of Group VI requires Formula IV while the method of Group VII requires Formula V. Thus, the

methods have different modes of operation. The structure and function of Formula IV and V are materially distinct and separate. The method of Group VI does not require Formula V and the method of Group VII does not require Formula IV. The burden required to search the method using either Formula IV or V would be undue.

Groups VI and VIII are patentably distinct because the method of Group VI requires Formula IV while the method of Group VIII requires Formula II. Thus, the methods have different modes of operation. The structure and function of Formula IV and II are materially distinct and separate. The method of Group VI does not require Formula II and the method of Group VIII does not require Formula IV. The burden required to search the method using either Formula IV or II would be undue.

Groups VII and VIII are patentably distinct because the method of Group VII requires Formula V while the method of Group VIII requires Formula II. Thus, the methods have different modes of operation. The structure and function of Formula V and II are materially distinct and separate. The method of Group VII does not require Formula II and the method of Group VIII does not require Formula V. The burden required to search the method using either Formula V or II would be undue. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for each Group is independent and separate, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

A gene encoding p53,

a gene encoding p110Rb,

a gene encoding p94Rb,

a gene encoding p56Rb,

a gene encoding p16, and

a gene encoding p21.

It is assumed that Rb56 is equivalent to p56Rb.

See claim 63.

If applicants elect Groups V, VI, VII or VIII, applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 61-81 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 872-9306.

Michael C. Wilson

MICHAEL WILSON
PRIMARY EXAMINER